

VII. 510(k) Summary of Safety and Effectiveness

K960391

General Information

Manufacturer: Strato/Infusaid Inc.
1400 Providence Highway
Norwood, MA 02167

JUL - 3 1996

Contact Person: Craig M. Audet
Director, Worldwide Regulatory Affairs
Telephone #(617) 255-6765

Date Prepared: January 25, 1996

Device Name

Proprietary Name: Strato/Infusaid PeriPort Infusion Set
Model Nos. 41770, 41771

Classification Name: Infusion Set, Administration, Intravascular

Predicate Devices

Strato/Infusaid LifePort Infusion Set
Model No. LPS 3004, LPS 3005, LPS 3006, LPS 3007, LPS 3008, LPS
3009, LPS 3017, LPS 3023, LPS 3025

Strato/Infusaid Infuse-a-Port Winged Infusion Set
Model Nos. 41129-1, 41129-2, 41129-3, 41129-4, 41129-5

Product Description

The Strato/Infusaid PeriPort Infusion Set is a device designed to provide straight needle access to the Strato/Infusaid PeriPort System for the infusion of drugs and fluids into the vascular access system.

Indications for Use

The Strato/Infusaid PeriPort Infusion Set is indicated for the infusion of drugs and fluids into the Strato/Infusaid PeriPort Peripheral Access Device.

Substantial Equivalence

The subject Strato/Infusaid PeriPort Infusion Set is substantially equivalent to the commercially available Strato/Infusaid LifePort Infusion Set and the Strato/Infusaid Infuse-a-Port Winged Infusion Set.

The Strato/Infusaid PeriPort Infusion Set has the same indications, contraindications and design principles as the commercially available (substantially equivalent device), the Strato/Infusaid LifePort Infusion Set. The difference between the infusion sets is the wing design and straight vs. 90° needle.

The Strato/Infusaid PeriPort Infusion Set has the same indications, contraindications and design principles as the commercially available (substantially equivalent device), the Strato/Infusaid Infuse-a-Port Winged Infusion Set. The difference between the infusion sets is the straight vs. 90° needle